REMARKS

This paper is responsive to the Supplemental Examiner's Answer, mailed November 25, 2008, which followed the remand by the Board of Patent Appeals and Interferences (decided March 28, 2008). As provided for by 37 C.F.R. § 41.50(a)(2)(i), Applicants have elected to reopen prosecution via the filing of this reply under 37 C.F.R. § 1.111.

Claims 1 - 15 are pending in the above-identified application. Claims 1, 2 and 11 have been amended. The amendments are supported throughout the specification as originally filed (*e.g.*, paragraph **[0089]** of the published application), and therefore, no new matter is added by these amendments. Reexamination and reconsideration of the pending claims are respectfully requested.

Rejections Under 35 USC 102

Claims 1-5, 7, 9, 11, and 14 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 4,848,340 to Bille *et al.* (hereinafter "the '340 patent"). Such rejections are traversed in part and overcome in part as follows.

While Applicants respectfully disagree with the rejections and do not acquiesce to the reasoning provided, claims 1, 2 and 11 have been amended to expedite prosecution of the present case. As will be discussed below for each of the independent claims, the cited reference fails to teach or suggest each and every element of the invention recited by the claims, thereby precluding the establishment of a *prima facie* case of anticipation.

Independent Claim 1 (Dependent Claims 2-5, 7 and 9)

Independent claim 1 reads as follows:

> A laser surgery system for treating a tissue located at a site of an eye, the system comprising:
>
> a laser making a beam of a treatment light energy, the treatment light energy comprising corneal ablation light energy deliverable to the site so as to effect reshaping of a corneal tissue at the site;
>
> an imaging system projecting an image of a natural tissue structure, the natural tissue structure being in proximity to the site, the image of the site

> being visible to the user and indicating an X-Y position of the natural tissue structure along X and Y directions transverse to the beam;
>
> a light detector having the image of the structure projected thereon and generating a first electrical signal in response to the image of the structure, the first signal being related to the X-Y position of the structure; and
>
> a processor adapted to generate a second electrical signal in response to the first electrical signal, the second signal stabilizing the beam of treatment light energy delivered to the tissue treatment site in the X and Y directions as the light energy is delivered to the tissue treatment site.
> (Emphasis added)

The '340 patent fails to teach or suggest every element of the invention recited in claim 1. In particular, the '340 patent fails to teach "an imaging system projecting an image of a natural tissue structure, the natural tissue structure being in proximity to the site, the image of the site being visible to the user and indicating an X-Y position of the natural tissue structure along X and Y directions transverse to the beam," and "a light detector having the image of the structure projected thereon and generating a first electrical signal in response to the image of the structure, the first signal being related to the X-Y position of the structure." These elements are recited in independent claim 1 and incorporated into corresponding dependent claims 2-5, 7 and 9. Moreover, these elements are supported throughout the specification (see, e.g., Figures 5, 6, 9D, 9E, and 10). Attention is respectfully drawn, for example, to the exemplary embodiment illustrated in Figure 5 and the corresponding discussion in paragraph **[0089]** in the published application.

The '340 patent discloses two approaches for tracking the movement of a patient's eye. With regard to the first approach, the '340 patent states:

> A preferred embodiment of the novel eyetracker comprises a visual light source on which a patient can fixate to coaxially align the visual axis of the patient's eye with a segment of the axis of the visual light beam. A laser source also coaxially aims its beam along this axis segment of the visual light beam. Thus, when the patient's eye is fixated, a reference alignment is established between the eye's visual axis and the laser beam since the eye's visual axis and the laser beam are both coaxially aligned on the same axis segment. While the patient's eye is initially in reference alignment, the laser source is activated to mark a grid on the cornea of the

patient's eye which fixes a known relationship between the grid and the eye's visual axis.

A source of diffused infrared light is provided to illuminate the grid marked cornea. Reflections therefrom are optically directed to a sensor where movements of the grid out of its reference alignment are detected. At the sensor, variations in the intensity of the reflected infrared light are used to generate signals which are representative of any grid movement. These signals are then transmitted by electronic means from the sensor to a comparator. In the comparator, each grid movement signal is compared with a reference signal which is representative of the grid position when in reference alignment. An error signal, proportional to the difference between the "grid in reference alignment" signal and the "grid movement" signal, is generated and transmitted to a guidance system which steers the laser beam in a manner that reduces the error signal to a null. While maintaining the error signal at a null, the laser beam is steered to make controlled external or internal ablations of the cornea in accordance with a predetermined computerized program. (col. 2, lines 7-41 (emphasis added)).

With regard to the second disclosed approach, the '340 patent states:

In addition to the use of diffused infrared light for monitoring grid movement to establish a closed loop feedback control for the laser guidance system, the source of diffused infrared light may also be used to help identify the eye's axis of symmetry. For this latter purpose, the sensor is focused on the plane of the iris rather than on the cornea. When focused on the plane of the iris, the sensor is focused along a plurality of lines to detect the intensity of the light that is reflected from the sclera, the iris and the pupil. The sensor then transmits this information to a computer which uses it to precisely determine the exact relationship between sclera, iris and pupil. Also, a beam of collimated infrared light from a laser diode is focused onto the cornea. In alternation with its focus on the iris plane, **the sensor is focused on the cornea to *scan* the cornea** and detect specular reflections from the beam of collimated infrared light. Due to the shape of the cornea, the specular reflection of greatest intensity will come from the apex of the cornea. **Since the sensor is preferably a line diode**, the apex of the cornea is identified ***when*** the most intense specular reflection falls on the center of the line diode. This information is also sent to the comparator where information from the iris plane concerning the relationship of the sclera, iris and pupil, and information from the corneal plane concerning the apex of the cornea are used together to determine the eye's axis of symmetry. (col. 2, lines 42-69) (**emphasis** added).

In both of the disclosed approaches, the '340 patent uses a galvonometric mirror to provide the sensor (*i.e.*, linear diode) with a scanning coverage of the eye. With regard to the first approach, the '340 patent states:

> The infrared light reflected from cornea 30 with information regarding **grid** 60 is reflected by galvanometric mirror 70 where it is directed to pass through a pair of convex lenses 72a and 72b. After passing through convex lenses 72 a and 72b, this infrared light is incident on 50% mirror 74 where half the light is passed toward linear diode 76. Linear diode 76 is preferably a line of individual light sensitive sensors or pixels. Thus, galvanometric mirror 70 can be continuously rotated in a well known manner **to provide linear diode 76 with a scanning coverage of eye 20**. Signals generated by such a device can then be used in a manner well known in the art. (col. 5, line 66 through col. 6, line 10) (**emphasis** added).

With regard to the second approach, the '340 patent states:

> As previously indicated, galvanometric mirror 70 is moveable **to scan the beam of collimated light from source 78 along scan lines on cornea 30**. Reflections of light from these scan lines are detectable by linear diode 76 and information contained in the reflections can be transmitted to comparator 28 for use by device 10. Specifically, this use relates to identification of the symmetrical axis of eye 20 in a manner to be disclosed below. (col. 6, lines 36-44 (**emphasis** added).

Hence, per the actual disclosure of the reference, the '340 patent discloses the use of a scanning system to provide a one-dimensional sensor with a scanning coverage of the eye. As such, the '340 patent fails to disclose or suggest "a light detector having the image of the structure projected thereon and generating a first electrical signal in response to the image of the structure, the first signal being related to the X-Y position of the structure." In other words, the '340 patent fails to disclose projecting the recited image of the structure onto a light detector and having the light detector process the image so as to generate a signal related to the X-Y position of the structure.

The present application discloses a system that provides advantages that are not provided by the system disclosed in the '340 patent. The present application provides a system

that can provide indication of positions of a natural tissue structure of an eye from a single image. In contrast, the tracking approaches disclosed in the '340 patent involve the processing of a data obtained during a series of temporally spaced scans of the eye, during which the eye may have moved between scans thereby complicating any determination of the position of the eye as well as degrading the accuracy of the positional determination.

The '340 patent further fails to teach or suggest "an imaging system projecting an image of a natural tissue structure, the natural tissue structure being in proximity to the site, the image of the site being visible to the user and indicating an X-Y position of the natural tissue structure along X and Y directions transverse to the beam" as recited in claim 1. In particular, the '340 patent fails to disclose a system that makes the image of the site visible to the user. Applicants respectfully submit that the Supplemental Examiner's Answer fails to articulate how the '340 patent discloses a system that makes the image of the site visible to the user. Nor does the '340 patent disclose projecting an image of a natural tissue structure that indicates an X-Y position of the natural structure. In contrast, as discussed above, the '340 patent disclose the use of a scanning system to provide a one-dimensional sensor with a scanning coverage of the eye, which involves a series of temporally spaced scans as opposed to the recited image.

For the reasons set forth above, Applicants respectfully submit that a *prima facie* case of anticipation has not been established. The '340 patent does not teach each and every element of independent claim 1. Thus, claim 1 is patentable over the '340 patent. Claims 2-5, 7, and 9 are patentable over the '340 patent at least for depending from claim 1, as well as on their own merits. Accordingly, Applicants respectfully request that the rejection of claims 1-5, 7, and 9 under 35 U.S.C. §102(b) be withdrawn and the claims allowed.

Independent Claim 11 (Dependent Claim 14)

Independent claim 11 reads as follows:

> A method of treating a tissue located at a site of an eye of a patient with a laser, the tissue treatment site being seen by a user, the method comprising:

making a beam of a corneal reshaping treatment light energy with the laser, the treatment light energy being deliverable to the tissue treatment site so as to treat a cornea;

projecting a real-time image of the tissue treatment site and an image of a natural tissue structure with an optical system, the natural tissue structure being in proximity to the tissue treatment site;

measuring an X-Y position of the tissue structure from a first electrical signal generated by a detector in response to the image, the detector having the image of the structure projected thereon, the first signal being related to the position of the structure along X and Y directions traverse to the beam;

generating a second electrical signal in response to the measured position of the structure, the second signal stabilizing the beam of treatment light energy in the X and Y directions as the treatment light energy is delivered to the tissue treatment site; and

transmitting the stabilized beam of treatment light energy to the tissue treatment site so as to alter refraction of the cornea.

(Emphasis added)

The '340 patent fails to teach or suggest every element of the invention recited in claim 11. In particular, the '340 patent fails to teach "projecting a real-time image of the tissue treatment site and an image of a natural tissue structure with an optical system, the natural tissue structure being in proximity to the tissue treatment site" and "measuring an X-Y position of the tissue structure from a first electrical signal generated by a detector in response to the image, the detector having the image of the structure projected thereon, the first signal being related to the position of the structure along X and Y directions traverse to the beam." In other words, the '340 patent fails to disclose projecting the recited real-time image onto a detector and having the detector process the image so as to generate a signal related to the X-Y position of the structure and measure the X-Y position of the structure from the signal. In contrast, as discussed above, the tracking approach disclosed in the '340 patent involves the processing of data obtained during a series of temporally spaced scans of the eye, which does not involve the processing of a real-time image as recited in claim 11.

For the reasons set forth above, Applicants respectfully submit that a *prima facie* case of anticipation has not been established. The '340 patent does not teach each and every element of independent claim 11. Thus, claim 11 is patentable over the '340 patent. Claim 14 is

patentable over the '340 patent at least for depending from claim 11, as well as on its own merits. Accordingly, Applicants respectfully request that the rejection of claims 11 and 14 under 35 U.S.C. §102(b) be withdrawn and the claims allowed.

Rejections Under 35 USC 103

Claims 1-7, 9, 11, and 14 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over the '340 patent in view of U.S. Patent No. 4,901,718 to Bille *et al.* (hereinafter "the '718 patent"). Applicants respectfully submit that the proposed combination of references, either alone or in combination, fails to teach or suggest all the elements of claims 1-7, 9, 11, and 14, thereby precluding the establishment of a *prima facie* case of obviousness. The '340 patent is traversed for at least the foregoing reasons. As noted above, the '340 patent fails to teach all elements of independent claims 1 and 11.

The '718 patent fails to provide the elements that are missing from '340 patent. The '718 patent refers to a laser beam guidance system that moves and focuses a laser beam in accordance with a pre-established program to photo-chemically affect cells in the cornea of the eye ('718 patent, Abstract.) The Examiner's Supplemental Answer states that "Bille et al. ('718) teaches a laser redirecting system to keep the surgical laser trained on the eye as the eye moves, including steering means for the X- and Y- directions and a focusing means. However, the '718 patent fails to teach the above discussed claim elements of independent claims 1 and 11 that are missing from the '340 patent, but instead is directed towards a guidance system that controls the laser beam itself, and is not directed towards systems and/or methods that provide eye movement tracking.

Therefore, independent claims 1 and 11 are patentable over the '340 patent and the '718 patent at least because these references, alone or in combination, fail to teach or suggest Applicants' claimed system and method. Claims 2-7, 9, and 14 are patentable over both references at least because they depend from claims 1 and 11, as well as on their own merits. Accordingly, Applicants respectfully request that the rejection of claims 1-7, 9, 11, and 14 under 35 U.S.C. §103(a) be withdrawn and the claims allowed.

Claims 10 and 15 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the '340 patent in combination with the '718 patent and further in view of U.S. Patent No. 5,090,798 to Kohayakawa (hereinafter "Kohayakawa"). Applicants respectfully submit that this rejection is erroneous for at least the same reasons set forth in the foregoing with respect to the non-obviousness of independent claims 1 and 11, from which claims 10 and 15 respectively depend. Moreover, the '718 patent and Kohayakawa, whether taken alone or in combination, fail to remedy the failings of the '340 patent set forth above. Therefore, if an independent claim is non-obvious under 35 U.S.C. §103, then any claim depending there-from is non-obvious. (*In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988).)

Moreover, Applicants respectfully submit that Kohayakawa fails to teach or suggest "a safety interrupt means for interrupting delivery of the laser beam to the patient when it is determined that the tracking means has lost the structure being tracked" as recited in claim 10, and fails to teach or suggest "automatically interrupting delivery of the laser beam to the tissue treatment site when it is determined via the processor that the sensor has lost the structure being tracked" as recited in claim 15. As an initial matter, Applicants respectfully submit that the rejection fails to indicate the particular portion of Kohayakawa where these elements are allegedly taught as required by 37 C.F.R. 1.104(c)(2). As understood by Applicants, Kohayakawa discloses an apparatus that can produce linear laser beams with desired intensity distributions along a line segment (See Abstract; FIGS. 1A and 2). The Background Section of Kohayakawa states:

> In U.S. Pat. No. 4,665,913, it is disclosed to scan a spot light beam on the cornea of an eye to be examined to thereby obtain a desired intensity distribution. However, the light scanning requires a varying amount of time, and this leads to the necessity of a cumbersome operation of temporarily stopping the application of the laser beam when the eye to be examined has moved and again applying the laser beam after alignment.

Given the failure of the rejection to cite to the particular portion of Kohayakawa that allegedly teaches the above noted elements, Applicants are assuming, based upon review of Kohayakawa, that the above statement forms the bases of the assertion that Kohayakawa teaches

the above noted elements from claim 10 and 15. However, Applicants respectfully submit that Kohayakawa fails to teach or suggest the above noted elements, which concern the interruption of the delivery of the laser beam upon the loss of tracking as opposed to a mere statement about interrupting delivery upon mere movement of the eye.

For the reasons set forth above, Applicants respectfully submit that a *prima facie* case of obviousness for claims 10 and 15 has not been established as the proposed combination of the '340 patent, the '718 patent, and Kohayakawa fails to teach or suggest all elements recited in claims 10 and 15. Accordingly, Applicants respectfully request that the rejection of claims 10 and 15 under 35 U.S.C. §103(a) be withdrawn and the claims allowed.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

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